UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte GARY L. GRIFFITHS

Appeal No. 2004-1660
Application No. 10/071,247

HEARD: December 9, 2004

Before WILLIAM F. SMITH, SCHEINER and GRIMES, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the final rejection of claims 9-12 and 16-20. Claims 13-15, also pending, have been objected to.

Claim 9 is representative:

9. A method for detecting a tissue comprising:
(a) administering to a patient a bispecific antibody or antibody fragment comprising an arm that is specific to a target tissue of the patient and another arm that is specific to an F-18-labeled peptide or a low molecular weight hapten conjugated to the F-18-labeled peptide; and allowing the bispecific antibody or antibody fragment to bind to the target tissue, and the non-targeted bispecific antibody or antibody fragment to clear;
(b) administering the F-18-labeled peptide or the hapten conjugate thereof to the patient, and allowing the F-18-labeled peptide or the hapten conjugate thereof to bind to the bispecific antibody or the antibody fragment, and the unbound F-18-labeled peptide or hapten conjugate thereof to clear; and
(c) detecting the F-18-labeled peptide, thereby detecting the target tissue.

Claims 9-12 and 16-20 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking both enablement and adequate written description. We will reverse both of these rejections.

BACKGROUND

> The present invention provides simple and efficient methods for incorporating the F-18 [(fluorine-18)] radionuclide into peptide-containing targeting vectors, such as proteins, antibodies, antibody fragments and receptor-targeted peptides . . . mak[ing] such targeting vectors available for routine clinical positron emission tomography.
>
> Of all nucleophiles present on peptides, only the free thiol group can be rapidly alkylated at neutral pH and moderate temperature. The present invention takes advantage of this unique property of free thiol groups, and provides methods for labeling thiol-containing peptides with F-18.

Specification, page 4.

> [A]ny thiol-containing peptide [can be labeled] . . .
>
> Peptides that originally do not comprise a free thiol group can be labeled . . . by first modifying the peptide to add a free thiol group by methods known to those skilled in the art . . .

Id., pages 5-6.

> [A] peptide that has been radiolabeled with F-18 as described above is delivered to a targeted tissue using a bispecific antibody (bsMAb) . . . containing at least one arm that is specific to the targeted tissue and at least one other arm that is specific to the F-18 labeled peptide . . .
>
> [T]he bsMAb . . . is administered to a patient and allowed to localize to the targeted tissue. Some time later (after the unbound bsMAb . . . is allowed to clear), the F-18-labeled peptide . . . is administered to the patient. Since at least one of the arms of the bsMAb . . . is specific to the F-18-labeled peptide . . . , the F-18-labeled peptide is also localized to the target. After the unbound F-18-labeled peptide . . . is allowed to clear, the target is then visualized by routine clinical positron emission tomography.

Id., pages 3-4.

DISCUSSION

The examiner rejected claims 9-12 and 16-20 under 35 U.S.C. § 112, first paragraph, as lacking both enablement and adequate written description in the specification for anything other than methods requiring "specific F-18 labeled peptide[s] such as the ones recited [on page 4 of the specification]" (Answer, page 3).

Enablement

"The first paragraph of 35 U.S.C. § 112 requires, inter alia, that the specification of a patent enable any person skilled in the art to which it pertains to make and use the claimed invention. Although the statute does not say so, enablement requires that the specification teach those in the art to make and use the invention without 'undue experimentation.' In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). That some experimentation may be required is not fatal; the issue is whether the amount of experimentation is 'undue.'" In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991) (emphasis in original).[1] Nevertheless, "[w]hen rejecting a claim under the enablement requirement of section 112," it is well settled that "the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement." In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

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[1]

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman [230 USPQ 546, 547 (BdPatAppInt 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims (footnote omitted).
>
> In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Thus, the issue here is not whether appellants has established that the disclosure is broadly enabling for the scope of the claims; the issue is whether the PTO has met its "initial burden of setting forth a reasonable explanation as to why" it is not.

In the present case, the examiner focuses primarily on the breadth of the claims. While we agree with the examiner that the claims are generic in their requirement for bispecific antibodies with one arm directed against an unspecified target tissue, and the other arm directed against an unspecified F-18-labeled peptide, frankly, we fail to see the problem. The examiner does not appear to question the ability of one skilled in the art to produce bispecific antibodies directed to any number of antigens (e.g., tissue markers of interest or peptides-to-be-labeled), despite a certain recognized element of unpredictability; nor does the examiner appear to question the ability of one skilled in the art to use the protocol outlined in the specification to label any given peptide with F-18. To the extent the examiner believes that the specification must "teach how to make and use all bispecific . . . antibod[ies] . . . where one arm is specific for all target tissue of the patient and the other arm is specific for all undisclosed F-18-labeled peptide[s]" (Answer, pages 4-5), we note that no authority has been cited in support of this requirement. On the contrary, "appellants are not required to disclose every species encompassed by their claims even in an unpredictable art." In re Angstadt, 537 F.2d 498, 504, 190 USPQ 214, 218 (CCPA 1976) (emphasis in the original).

In our view, the reasons given by the examiner in support of the enablement rejection do not begin to provide an adequate basis to question the adequacy of appellant's disclosure. The rejection of the claims for lack of enablement under 35 U.S.C. § 112, first paragraph, is reversed.

Written Description

Compliance with the written description provision of 35 U.S.C. § 112, first paragraph requires sufficient information in the original disclosure to show that the inventor possessed the invention at the time of the original filing. See Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1561, 19 USPQ2d 1111, 1115 (CAFC 1991) ("Adequate description of the invention guards against the inventor's overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation"). Stated differently, applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. "The written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [applicant] invented what is claimed.'" Union Oil Co. of Cal. V. Atlantic Richfield Co., 208 F.3d 989, 997, 54 USPQ2d 1227, 1232 (Fed. Cir. 2000) (citation omitted).

The examiner notes that the specification discloses "only three F-18-labeled peptides, [and] there is a lack of a written description of all additional F-18-labeled peptide[s] . . . , let alone all bispecific antibodies that bind[ ] to all tissue[s] and all F-18-labeled peptide[s] for a method for detecting a tissue by positron emission tomography" (Answer, page 7). The examiner believes that "[o]ne of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus[,] [t]hus, Applicant was not in possession of the claimed genus" (Answer, pages 7-8).

We disagree. There is no dispute that peptide:antibody binding pairs, tissue marker:antibody binding pairs, and bispecific antibodies are all well-known in the art. In our view, one of ordinary skill in the art would readily understand that appellant, in describing a method of making and using three specific F-18-labeled peptides, and a method of making and using bispecific antibodies for a two-step imaging process, had possession of the genus of bispecific antibodies required by the claims at the time of filing.

The examiner has failed to establish that one of ordinary skill in the art would not have recognized that appellant invented what is claimed. The rejection of the claims for lack of written description under 35 U.S.C. § 112, first paragraph, is reversed.

REVERSED

William F. Smith)
Administrative Patent Judge)
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Toni R. Scheiner) BOARD OF PATENT
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Toni R. Scheiner) APPEALS AND
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